

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

<p>IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION</p>	
<p>THIS DOCUMENT RELATES TO:</p> <p><i>The City of New York v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 04-CV-06054</p> <p><i>County of Albany v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0425</p> <p><i>County of Allegany v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0236</p> <p><i>County of Broome v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0456</p> <p><i>County of Cattaraugus v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0256</p> <p><i>County of Cayuga v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0423</p> <p><i>County of Chautauqua v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0214</p> <p><i>County of Chemung v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-6744</p> <p><i>County of Chenango v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0354</p> <p><i>County of Columbia v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0867</p> <p><i>County of Cortland v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0881</p> <p><i>County of Dutchess v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 05-CV-6458</p> <p><i>County of Essex v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0878</p> <p><i>County of Fulton v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0519</p>	<p>MDL NO. 1456 Civil Action No. 01-12257-PBS</p> <p>Judge Patti B. Saris</p> <p><b>PLAINTIFFS' OPPOSITION TO SEPARATE MEMORANDUM OF MERCK &amp; CO., IN SUPPORT OF MOTION TO DISMISS</b></p>

*County of Genesee v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-00267

*County of Greene v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0474

*County of Herkimer v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-00415

*County of Jefferson v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0715

*County of Lewis v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0839

*County of Madison v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-00714

*County of Monroe v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6148

*County of Nassau v. Abbott Laboratories, Inc., et al.*  
E.D.N.Y. Case No. 04-CV-05126

*County of Niagara v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-06296

*County of Oneida v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0489

*County of Onondaga v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0088

*County of Ontario v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6373

*County of Orleans v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6371

*County of Putnam v. Abbott Laboratories, Inc., et al.*  
S.D.N.Y. Case No. 05-CV-04740

*County of Rensselaer v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-00422

*County of Rockland v. Abbott Laboratories, Inc., et al.*  
S.D.N.Y. Case No. 03-CV-7055

*County of Schuyler v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6387

*County of Seneca v. Abbott Laboratories, Inc., et al.*

W.D.N.Y. Case No. 05-CV-6370

*County of St. Lawrence v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0479

*County of Saratoga v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0478

*County of Steuben v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6223

*County of Suffolk v. Abbott Laboratories, Inc., et al.*  
E.D.N.Y. Case No. 03-CV-12257

*County of Tompkins v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0397

*County of Ulster v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 06-CV-0123

*County of Warren v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0468

*County of Washington v. Abbott Laboratories, Inc., et al.*  
N.D.N.Y. Case No. 05-CV-0408

*County of Wayne v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-06138

*County of Westchester v. Abbott Laboratories, Inc., et al.*  
S.D.N.Y. Case No. 03-CV-6178

*County of Wyoming v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-6379

*County of Yates v. Abbott Laboratories, Inc., et al.*  
W.D.N.Y. Case No. 05-CV-06172

## INTRODUCTION

Defendant Merck and Co., Inc. (“Merck”) asserts in its individual memorandum (“Merck MTD”) that (i) this Court dismissed all of Suffolk County’s claims against it, and (ii) plaintiffs failed to meet the particularity requirement of Fed. R. Civ. P. 9(b) for the same AWP and Best Price claims. Merck is wrong on both counts. First, as explained in plaintiffs’ opposition to the consolidated motion to dismiss (“Cons. Opp.”), the Court did not dismiss Suffolk’s AWP-based unjust enrichment claims against the Suffolk 13 + 6 (which included Merck) or Suffolk’s claim under N.Y.C. R. R. 515.2(b)(4) and (5).<sup>1</sup>

Second, in arguing that plaintiffs fail to meet Rule 9(b) requirements, Merck says the Consolidated Complaint (“CC”), “does not say why the [alleged price differences] constitute fraud.” Merck MTD at 2. Merck also contends that the CC fails to satisfy 9(b) with respect to its Best Price/Rebate allegations because the CC discusses adjudicated and irrelevant investigations which cannot support an allegation of fraud. *See id.* at 3-5.

Merck’s arguments ignore entirely the particularity rulings of this court and instead depend on cases that are less analogous.<sup>2</sup> As detailed below and in Exhibit A to the Cons. Opp., plaintiffs’ allegations have more than satisfied Rule 9(b) requirements by detailing the circumstances surrounding Merck’s fraudulent 1) reporting of grossly inflated AWPs and other pricing information and 2) exclusion of deeply discounted drug sales from its Best Price claims.

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<sup>1</sup>See Cons. Opp. at Procedural History Section; *see also*, *In re Pharm. Indus. Average Wholesale Price Litig.*, 339 F.Supp.2d 165, 181, 183 (D. Mass. Sep. 30, 2004)(“*Suffolk I*”) and, *In re Pharm. Indus. Average Wholesale Price Litig.*, 2004 WL 2387125 at \*2 (D. Mass. Oct. 26, 2004)(“*Suffolk II*”).

<sup>2</sup>This is especially true in respect to Merck’s characterization of plaintiffs’ Best Price/Rebate claims, where Merck entirely disregards the Court’s prior rulings detailing the requirements of 9(b). *See Suffolk II* at \*2. In *Suffolk II*, the Court held that to plead a Best Price claim, “plaintiffs must allege sufficient facts regarding the circumstances of the fraudulent rebate scheme with respect to each Defendant. ... Plaintiff has failed to set forth at least minimal facts with respect to (1) the allegedly fraudulent or false price reported to the state for any specific drug; or (2) any information showing a company-wide scheme to misstate Best Prices....” *Id.*  
(continued...)

## ARGUMENT

### I. The Consolidated Complaint Adequately Alleges How Merck's Price Inflation Scheme Damages Medicaid And Satisfies Fed. R. Civ. P. 9(b)

#### A. Rule 9(b) Requirements

Merck makes no reference to the Court's prior particularity rulings in its motion. *See* Merck MTD at 3 (quoting *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 226 (1st Cir. 2004) and *Massachusetts v. Mylan Laboratories*, No. 03-11865-PBS, Mem. at 2 (D. Mass. Apr. 5, 2005)). In its prior opinions, the Court ruled that Rule 9(b)'s particularity requirements regarding AWP claims are satisfied where plaintiff provides:

- 1) A spread which plaintiff possesses a good-faith basis to calculate<sup>3</sup> or, alternatively,
- 2) A detailed overview of the fraudulent scheme that fits the "paradigm described in the complaint" *See Suffolk I*, 307 F.Supp., at 208, *citing to In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F.Supp.2d 172, 194 (D.Mass. 2003); and
- 3) "[W]ith respect to each defendant, 1) the specific drug or drugs that were purchased from defendant, 2) the allegedly fraudulent AWP for each drug and 3) the name of the specific plaintiffs that purchased the drug." *See id.*

Merck ignores these rulings and states that the CC fails to meet Rule 9(b) requirements because it fails to state why the alleged price differences constitute AWP fraud. Merck MTD at 2 (emphasis added). Merck selectively summarizes portions of the CC's allegations, and then claims that no explanation is given as to why these allegations amount to fraud.<sup>4</sup> *See* MTD at 1-5.

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<sup>3</sup>In *Suffolk II*, 2004 WL 2387125, at \*2 (D.Mass. 2004) the court held that in the absence of allegations particularizing the circumstances surrounding the price reporting, Suffolk could satisfy 9(b) simply by alleging a spread for which it has "a good-faith basis". *See Id.*, ("[t]he so-called "Suffolk 13" ...insist that the allegations concerning the spread are not particular enough because ... there are no ...allegations (e.g., government investigations or the company's own internal documents) to support a claim of fraudulent pricing.... If there is a good faith basis for calculating a spread, the Court will deny the motion to dismiss.")

<sup>4</sup>The CCs allegations applicable to all defendants is a particular, detailed, and nuanced presentation of the facts underlying the counties' claims that are applicable to all defendants. These allegations cover 50 pages. In its summary of plaintiffs allegations, Merck cited only a single paragraph, and ignored the other 50 pages of allegations. *See* MTD at (continued...)

**B. Rule 9(b) Applied to AWP**

Merck's characterization of the CC's pleadings is entirely misleading and improper because the Counties pled in detail the fraudulent price manipulation scheme engaged in by *Merck and all defendants*. The CC alleges that Merck has reported intentionally false and misleading wholesale price information on which Medicaid reimbursements are based in order to market the spread with the intention of seizing market share from competitors. CC at ¶ 9, 12, 122-136. The "spread" is "the difference between the actual acquisition cost of a drug and the amount at which the drug is reimbursed." *Id.* at ¶ 9. Plaintiffs have alleged that Merck specifically reported "false and misleading wholesale price information" for its drugs. CC at ¶ 597. Plaintiffs allege that Merck knew it could market the spread to increase its market share and so marketed its products, (*Id.* at ¶ 599, Exhibit B-21). Plaintiffs further allege each NDC at issue, its fraudulent AWP, and its purchase by the Counties. *See* Exh. A to the CC at 50-52. Finally, the Counties set forth those NDCs for which the Counties' investigation had already shown Merck's pricing to be fraudulently misleading by listing those drugs whose AWP exceeded transaction prices by greater than 40% in 2000. *See* Exhibit B-21; *see also* CC at ¶¶ 124-127. These specific allegations, combined with the general allegations recited above, more than adequately particularize Merck's AWP fraud. They demonstrate exactly how the fraud works, both by explaining the scheme and providing specific examples of fraudulent pricing. Nassau County has properly alleged an AWP claim in accordance with Rule 9(b) by similar methods.<sup>5</sup>

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2, citing to CC ¶124.

<sup>5</sup>Merck forwards two arguments that are specifically directed at Nassau County. First, it claims that the Nassau Second Amended Complaint ("Nassau SAC" or "NSAC") does not explain why the alleged differences between the AWP and actual pricing constitute fraud as to Merck products, Mefoxin and Pepcid, noted in Exhibit A. Merck MTD at 2. Second, it contends that Nassau has not alleged payment for any Merck drugs because Mefoxin is not listed in Exhibit B and the form of Pepcid listed in Exhibit B is not listed in Exhibit A. *Id.* The evidence presented by Nassau (continued...)



## II. The Consolidated Complaint Adequately Alleges a Best Price Claim

Merck states that plaintiffs have not adequately alleged a Best Price Claim. See MTD at 4, citing to Joint Memorandum Point IV.B. This is untrue.<sup>6</sup>

Plaintiffs first provide general allegations of how the rebate program functions, and how Medicaid rebates are fraudulently lowered by defendant's misconduct of reporting false and inflated Best Prices. See CC at ¶¶21-26. Plaintiffs cited Merck's misconduct as an example. *Id.* at ¶ 23. The specific facts of the rebate program and the details of the Best Price scheme, (in a nutshell to "knowingly calculate its Best Prices excluding factors that it was statutorily and/or contractually required to include, resulting in the payments of rebates that were less than required") are alleged in detail in CC ¶¶ 146-154. See also ¶¶ 601-606.

Moreover, as detailed above, the court ruled that 9(b) requires that plaintiffs tie the Best Prices claims to particular drugs, discounts or other company-specific practices which support an inference of misrepresenting Best Prices. See *Suffolk II*, 2004 WL 2387125 at \*2. Here, the CC does exactly that with respect to the Merck drugs Pepcid, Zocor and Vioxx.

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is sufficient to state a claim against Merck because Nassau has alleged both the purchase of Merck drugs and Merck's use of inflated and fraudulent AWP over the market price.

Nassau has established facts to allege that the difference between the AWP and market price for Merck drugs is artificially inflated. While it has been established that the AWP is based on the WAC or direct prices, to which the publisher applies a standard 20 or 25% markup, Nassau alleges spreads greater than 25% for several of Merck's drugs. See NSAC Ex. A. The data provided regarding defendant drugs are but a small subset of the data that is potentially within the control of the defendants. Further, the Nassau complaint squarely addresses the role of Exhibits A and B. Exhibit A contains information on reported AWPs and generally available market prices for drugs that are produced by Merck. Exhibit B contains information on drugs purchased by Nassau in 2003. "Exhibit B does not include information for every drug for which Nassau County claims to have overpaid. Defendants control the information Nassau County would need to create a comprehensive list." NSAC at ¶183 n.7. Since the AWPs and price information for Mefoxin and Pepcid are from December of 2000, and the data contained in Exhibit B are reflective of information from 2003, the two sets of data do not, and furthermore are not required to, align.

<sup>6</sup>The Court held that 9(b) would be satisfied by pleadings which 1) tie the Best Prices claims to particular drugs, discounts or other company-specific practices which would support an inference of misrepresenting Best Prices, and/or 2) allege sufficient facts regarding the circumstances of the fraudulent rebate scheme with respect to each defendant, and/or 3) set forth at least minimal facts with respect to (i) the allegedly fraudulent or false price reported to the state for any specific drug; or (ii) any information showing a company-wide scheme to misstate Best Prices. See *Suffolk II*, 2004 WL 2387125 at \*2.

Conforming to the Court's rulings on 9(b), the CC alleges the following facts about the "particular drugs, discounts and company practices" for which the CC details Best Price misconduct:

- a) Vioxx, Zocor and Pepcid were sold by Merck to various hospitals at discounts that exceeded 90% of AWP as part of Merck's nominal pricing practices, including the Flex-NP program (*see* CC at ¶ 601, 602, 603, 604, 606);
- b) Zocor was sold for around .28 cents per pill during time periods when Merck reported a Best Price for Zocor of \$2.30 per pill (*see id.* at ¶602);
- c) Merck sold 20 mg Pepcid tablets to East Jefferson General Hospital for \$0.10 per pill while reporting an AWP of \$1.95 for the same pill (*see id.* at ¶ 603, 604); and
- d) Merck did not reflect these discounted prices in its best price calculations (*see id.*).

These allegations of "particular drugs, discounts and company practices" satisfy Rule 9(b) as they allege a pattern of Best Price fraud. *See Suffolk II*, 2004 WL 2387125 at \*2.

Merck misleadingly states that plaintiffs' Best Price allegations amount to nothing more than "unadjudicated qui tam complaints." Merck MTD at 4. However, plaintiffs do not rely merely on allegations in other complaints. Rather, plaintiffs' allegations are based on documentary exhibits filed in other litigations and a Wall Street Journal report detailing the difference between discounts and the Merck's reported best price.<sup>7</sup> Merck's point carries no weight, as the pleadings bring specific documentary evidence.

Merck's final point is that all evidence of discounting is irrelevant to an AWP claim. MTD at 4. But if drugs sold pursuant to Merck's nominal pricing programs are reimbursed by Medicaid, then Merck's discounting is relevant to both AWP and Best Price fraud. The complaints clearly allege that all discounted drugs (nominally priced drugs included) should in Merck's calculations of average wholesale prices. *See* CC at ¶¶ 604, 606 (stating that Merck did not account for the deeply discounted prices for Vioxx, Pepcid and Zocor in its Best Price or AWP calculations).

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<sup>7</sup> *See* ¶¶ 602 ("Merck documents reveal widespread discounting... *See* Deep Discounts by Drug Firms Draw Scrutiny"), ¶ 603 (citing to fn. 17, which cites Exhibit P, Relator's Brief In Opposition To Motion To Dismiss, *U.S. Ex. Rel.* (continued...))



**Conclusion**

For the reasons set forth herein, Merck' motion to dismiss should be denied in its entirety.

Dated: April 17, 2006.

Respectfully submitted,

**City of New York and all captioned Counties  
except Nassau, by**

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*William St. John LaCorte, MD v. Merck and Company, Inc.*, No. 99-3807, (E.D.L.A., filed July 16, 2003), for the proposition that Merck sold 20 mg Pepcid tablets at \$0.10, or less than 10% of AMP or AWP).

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